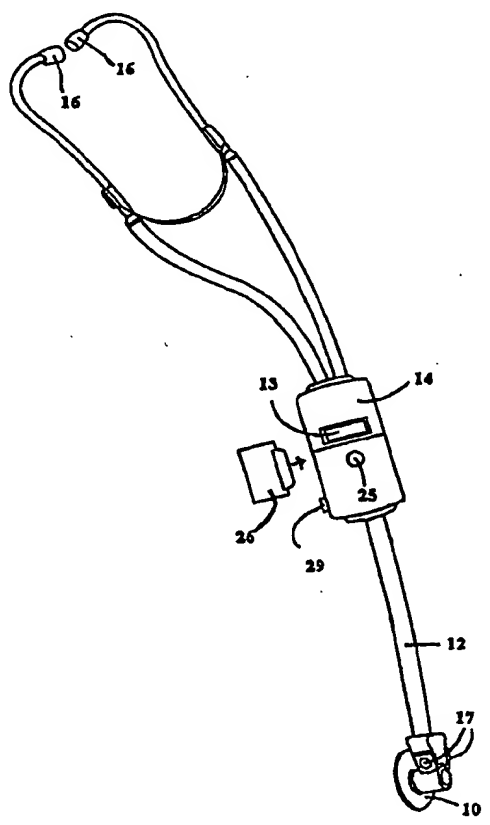


PCTWORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61B 7/04, 5/024	A1	(11) International Publication Number: WO 97/00045 (43) International Publication Date: 3 January 1997 (03.01.97)
(21) International Application Number: PCT/CA96/00408 (22) International Filing Date: 17 June 1996 (17.06.96) (30) Priority Data: 2,151,966 16 June 1995 (16.06.95) CA (71) Applicant: HEART SOUNDS INC. [CA/CA]; Unit 314, 801 York Mills Road, Don Mills, Ontario M3B 1X7 (CA). (72) Inventor: HART, Katz; Unit 314, 801 York Mills Road, Don Mills, Ontario M3B 1X7 (CA). (74) Agent: SAFFREY, Harold, A.; Suite 1704, 55 University Avenue, Toronto, Ontario M5J 2H7 (CA).		(81) Designated States: AL, AM, AU, AZ, BB, BG, BR, BY, CN, CZ, EE, FI, GE, HU, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, RO, RU, SD, SG, SI, SK, TJ, TM, TR, TT, UA, UG, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
(54) Title: STETHOSCOPE (57) Abstract <p>This invention provides, in a stethoscope for examining the characteristic of sound waves made by a beating heart, an electronic heart rate sensing device comprising: a wave-form component for producing a wave form that tracks the wave form of sound produced by the heart as derived from stethoscope contact with the patient in the area of the heart; a threshold establisher for establishing a wave form threshold beyond which cyclic reference complexes appear and are identified; a time measurement device for measuring the time elapsed between similar moments on adjacent reference complexes as an indicator of rate of heartbeat; and means for converting the measurement of time elapsed to a reading of rate of heartbeat.</p> 		

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia	GB	United Kingdom	MW	Malawi
AT	Austria	GE	Georgia	MX	Mexico
AU	Australia	GN	Guinea	NE	Niger
BB	Barbados	GR	Greece	NL	Netherlands
BE	Belgium	HU	Hungary	NO	Norway
BF	Burkina Faso	IE	Ireland	NZ	New Zealand
BG	Bulgaria	IT	Italy	PL	Poland
BJ	Benin	JP	Japan	PT	Portugal
BR	Brazil	KE	Kenya	RO	Romania
BY	Belarus	KG	Kyrgyzstan	RU	Russian Federation
CA	Canada	KP	Democratic People's Republic of Korea	SD	Sudan
CF	Central African Republic	KR	Republic of Korea	SE	Sweden
CG	Congo	KZ	Kazakhstan	SG	Singapore
CH	Switzerland	LI	Liechtenstein	SI	Slovenia
CI	Côte d'Ivoire	LK	Sri Lanka	SK	Slovakia
CM	Cameroon	LR	Liberia	SN	Senegal
CN	China	LT	Lithuania	SZ	Swaziland
CS	Czechoslovakia	LU	Luxembourg	TD	Chad
CZ	Czech Republic	LV	Latvia	TG	Togo
DE	Germany	MC	Monaco	TJ	Tajikistan
DK	Denmark	MD	Republic of Moldova	TT	Trinidad and Tobago
EE	Estonia	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	UG	Uganda
FI	Finland	MN	Mongolia	US	United States of America
FR	France	MR	Mauritania	UZ	Uzbekistan
GA	Gabon			VN	Viet Nam

STETHOSCOPE

FIELD OF THE INVENTION

This invention relates to an electronic stethoscope for deriving a reading of heart rate from sounds made by the heart.

BACKGROUND OF THE INVENTION

Heart rate is the number of times that the cardiac cycle repeats itself over a specific period of time, conventionally a minute. It is usually measured from a pulse on the patient's neck or wrist and is derived from cyclic variations in blood pressure. To know heart rate while probing heart sound with a stethoscope would be useful, but not easy to obtain by known methods, because it must be measured in the midst of different sounds occurring within the same cardiac cycle. No one to my knowledge has previously derived heart rate from the sounds produced by the heart as measured by a stethoscope.

SUMMARY OF THE INVENTION

This invention has as its object the achievement of this feat and to thereby provide a substantial advance in the art of probative medicine with a stethoscope. The invention preferably uses a hybrid computer which accepts the analog sound wave form detected by the stethoscope and converts it to digital form, and then processes it to produce a digital output of heart rate.

The ability to measure heart rate in the computer can be combined with the ability to simultaneously convey to the user the customary sounds made by the heart. It can also be combined with the ability to make a simultaneous record of the sounds of

the heart and of heart beat rate.

According to this invention, there is provided in a stethoscope for examining the characteristic of sound waves made by a beating heart, an electronic heart rate sensing device comprising: means for producing a wave form that tracks the wave form of sound produced by the heart as derived from stethoscope contact with the patient in the area of the heart; means for establishing a wave form threshold beyond which cyclic reference complexes appear and are identified; means for measuring the time elapsed between similar moments on adjacent reference complexes as an indicator of rate of heart beat; and means for converting the measurement of time elapsed to a reading of rate of heartbeat.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be clearly understood after reading the following description given in conjunction with the drawings in which:

Figure 1 is an illustration of a stethoscope with a heartbeat rate indicator according to this invention.

Figure 2 is a sectional and side view illustration showing the means for processing the heart rate of the stethoscope of Figure 1;

Figure 3 is a representation of a sound wave form for a typical heart beat;

Figure 4 is the wave of Figure 3 full-wave rectified and illustrating the manner in which it is divided into time segments for the purpose of producing threshold amplitudes that detect cyclic complexes from which heart rate can be determined.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Figure 1 is an illustration of an electronic stethoscope according to this invention. It has a cup 10 that is placed over a patient in the area of the heart. The cup has a microphone that tracks the sound of the heart and conducts it through cable 12 to a receiver in the housing 14 for amplification and transmission to the ear phones 16 for a user. This much of the device is old and not part of the invention.

The sound detected by the microphone is also input to a digital computer in housing 14 that processes it and derives from it a reading of heart rate that is displayed in the display screen 13. The reading is updated every second.

10 The digital computer in the housing includes a micro-controller, an analog-digital converter to convert the analog wave form provide by the microphone to digital data that can be processed by the micro-controller. There is also provided a digital-analog converter which converts the digital data back to analog-wave form before transmission to the ear phones 16 for hearing.

20 The micro-controller is code-embedded with an algorithm for calculating heart rate, information which it then passes on to a display driver, which in turn causes the heart rate to be displayed on the display screen 13. In the preferred embodiment, a micro-controller having a speed of 3 MHz, a read-only memory of 12 kilobytes and a random access memory of 128 kilobytes is used. Such a microcontroller is inexpensive but yet permits data to be saved for periods of several seconds for processing before it is replaced by other incoming data. Preferably, the microcontroller is programmed to keep the data collected for periods of at least six seconds before erasing it from memory to make room for new data.

All data converted from analog to digital format can be stored on a removable storage disk 26, which is inserted into drive slot 27. In use, after a patient has been examined, the disk can be removed from drive slot 27 of the housing 14 and placed in a computer located at a remote site. There, the heart sounds can be played back at varying speeds and volumes. The removable storage disk 26 also provides a means for storing this recorded information in the patient's file. The inventor has found it convenient to transfer information in buffers which hold data collected in bunches of six second time periods to the removable storage disk 26.

10 The stethoscope can run off of a standard power source such as battery, which can be initiated by pressing start-up button 25, and the operation of the stethoscope's electronic features can be controlled by standard circuitry using switches 17 mounted to the cup 10. Ejection button 29 can be used to eject storage disk 26 from the housing 14. Further switches, like switch 25, can be added to the housing 14 for specific functions if required. The arrangement of the switch means is a matter of personal preference of the designer and is not part of the invention.

20 The derivation of a number indicative of heart rate from sound wave form has not been done before, to my knowledge, probably because of the unpredictable and irregular nature of the wave form. I have determined that there are cyclic reference complexes that can be isolated and that are common to practically all heart beats from which rate of heart beat can be determined accurately.

Figure 3 is a drawing of a wave form of a typical heartbeat. It has a lupp, generally referred to by the numeral 28, representing the systolic (contracting) actions of the heart and a dupp, generally referred to by the numeral 30, representing the diastolic (expanding) actions of the heart during the cardiac cycle. The periods between the systolic actions and the diastolic actions are generally referred to by the numeral 32.

For ease of illustration, the heart rate determinable from the wave-form illustrated is sixty cardiac cycles per minute, i.e. there is one cardiac cycle per second.

The lupp 28 is usually louder, longer and duller in sound than the dupp 30 and it is bigger on the graph. However, in some people, and in varying conditions for listening, the opposite is true. This and other differences do not interfere with the isolation of cyclic complexes associated with a maximum from which I calculate heart beat rate.

10 It will be noted that in Figure 3 that the wave form, as at 32, is substantially constant between lupp 28 and dupp 30 and between dupp 30 and lupp 28 formations. The heart makes substantially no noise here and the base line of the derived wave form is taken as zero at this level.

The operation of the invention will be described in association with the analog wave forms of figures 2 to 4 but it will be understood that in the preferred embodiment of the invention, as described above, the analog voltage representing the sound is fed to a hybrid computer that takes the transmitted wave form, converts it to digital form and does all of the measurements and calculations in digital form. Digital computers are inexpensive, compact and efficient and are preferred for my purpose but an understanding of the invention is more easily obtained from considering the analog wave forms.

20 The embodiment described determines heart beat rate by isolating reference complexes that are related to either a lupp 28 or a dupp 30 (whichever is the largest) complex of pulses and which occur once each cycle of the waveform.

In the embodiment of the invention illustrated, the full wave rectified wave form

of Figure 4 is divided into sequential time segments of one second each, separated by time segment dividers 33, 34 and 35. This time segment usually is long enough to include both a lupp and a dupp. The object is to identify the time between sequential cyclic complexes associated with a maximum amplitude of the wave and this is done by determining the maximum amplitude in a time segment and establishing a threshold amplitude across the next time segment that is below the maximum and above which a cyclic complex appears. The threshold amplitude must, for example, be well above the base line.

10 In the example of the drawings, numeral 36 refers to the maximum amplitude of the first one second time segment and a threshold amplitude 38 is established in the second time segment. Numeral 40 refers to the maximum amplitude in the second time segment and a threshold amplitude 42 is established in the third time segment. Numeral 44 is the maximum in the third time segment and numeral 46 refers to the threshold in the fourth time segment. This sequence is continuous. I have found that a threshold of .5 of the maximum measured works well.

It is apparent that the waveform will cross the threshold just before the maximum is reached, as is the case at 48, 50 and 52, and that the cross over is identified with the maximum. Further, the time between two adjacent maximums (under most conditions) represents the time of one cycle from which heart rate can be calculated.

20 As above indicated, it has been found that by establishing the threshold voltage at half of the maximum detected that reference complexes, each composed of separately grouped pulses that are illustrated as extending over the threshold, are identifiable which give an accurate indication of heart rate.

The relationship between the maximum and minimum or no noise amplitude is significant and an examination of the total time that the amplitude is above the

threshold in a predetermined time after crossover is significant as a test of a time cyclic maximum. Thus, the time durations of the reference pulses (i.e. the portion of the pulses of the reference complex having an amplitude greater than the threshold amplitude) over a testing period, commencing at the time of the first crossover as at 48, 50 or 52 for each reference complex, are added up and compared in proportion to the time of the testing period. For heart rates of between 40 and 170 (cardiac cycles per minute), the inventor has found a testing period of 100 milli-seconds satisfactory and that, if the time durations of the component pulses 34 added up constituted thirty per cent or more of that testing period, a bona fide threshold complex has been found. If
10 the sum is less than 30 per cent, the measured reference complex is probably not cyclically related and should be rejected for calculation. The algorithm then continues its search looking for the next intersection of the threshold.

After a bona fide reference complex has been located, the algorithm does not start looking for the next reference complex until after a refractory period has ended. The refractory period is taken as having begun at the same moment in time that the bona fide reference complex began and continues on long enough after the testing period has ended such that, in most cases, any other complex of the same cycle that would render an inaccurate reading of heart rate will have been passed over. At the end of the refractory period, both the amplitude of both the lupp and the dupp
20 complexes within the same cardiac cycle as the reference complex are substantially reduced to amplitude below the threshold. If the heart rate is greater than 170 beats or less than 40 beats per minute, then an adjustment has to be made to the length of the refractory period. For instance, for heart rates greater than 150, the testing period must be shortened. For heart rates less than 40, the testing period must be lengthened.

A reference complex should also be rejected for calculation of heart beat rate if a next following reference complex is not located within 1200 milliseconds from the start

of the time of measurement of a reference complex. That is taken as an indication that a cycle has been missed. In that case, the next second period is used to calculate a new maximum and the process is re-initialized. For heart rates that are less than 40 beats per minute, this 1200 millisecond period must be increased.

10 In practice, the heart sound wave will be input to a digital computer that will convert it to a corresponding voltage form, convert it to digital form and perform all of the other operations described above to finally supply a digital reading of heart beat rate per minute on its screen. It will full-wave rectify the waveform; divide the base into time segments of one second; determine the maximum amplitude in each second and determine from it the cut-off amplitude for the next following time segment; determine the cyclically related reference complexes for each cycle; use a testing period to check to see that each reference segment is a valid cyclically related complex and reject it from measurement if it is not; determine the time between the beginning of the reference complex in a first cardiac cycle and the beginning of the reference complex in the next following cardiac cycle; and calculate the heart beat rate per minute and display it on the window read-out dial. It will do these things every second (determine maximum amplitude to provide threshold for next second period) and every cardiac cycle (identify and calculate time difference between the beginning of consecutive reference complexes) on a continuing basis.

20 The computer calculates the heart beat rate from the cycle time as derived from the first crossover point of the rectified waveform on the threshold of two adjacent cycles and checks the validity of the cross-over point by measuring the total time the waveform is over the threshold in the first 100 milliseconds after cross-over and by checking for the expected occurrence of a next following reference complex after the refractory period has ended. It thus is an accurate measurement because measurements likely to be in error as based on a reference complex that is not cyclic have been eliminated.

Modifications to the device described are contemplated within the scope of the invention. The threshold line location, the length of the testing period, the proportion of pulse to testing period tested for, can all be varied to suit particular circumstances. Full wave rectification might be eliminated by putting a threshold amplitude line below the base line and adding the times of amplitude across over above and below the line. The crucial aspect is to break out cyclic complexes at regular intervals from which heart rate can be calculated and to provide means for checking the validity of these complexes as being cyclically related to ensure accuracy.

The embodiments of the present invention in which an exclusive property or privilege claimed are defined as follows:

1. In a stethoscope for examining the characteristic of sound waves made by a beating heart, an electronic heart rate sensing device comprising:

means for producing a wave form that tracks the wave form of sound produced by the heart as derived from stethoscope contact with the patient in the area of the heart;

means for establishing a wave form threshold beyond which cyclic reference complexes appear and are identified;

10 means for measuring the time elapsed between similar moments on adjacent reference complexes as an indicator of rate of heart beat;

means for converting the measurement of time elapsed to a reading of rate of heartbeat.

2. In a stethoscope having means for producing an electronics wave form that tracks the form of the sound made by a patient's heart;

means for processing the wave form to determine the heartbeat rate by dividing it into sequential time segments;

20 determining the maximum amplitude in a time segment and establishing a threshold amplitude across the next time segment that is below the maximum amplitude and above which a cyclic complex associated with the maximum appears;

determining the time elapsed between two adjacent crossings of a threshold by the cyclic complex of the waveform; and

determining the heartbeat rate from the time elapsed.

3. In a stethoscope as claimed in claim 2 wherein the base of said wave form is close to the minimum noise level of the sound wave of the heart and said wave

form is full wave rectified.

4. In a stethoscope as claimed in claim 1, 2 or 3 having means for checking that the determined time elapsed is related to the time between similar moments on two adjacent cyclic complexes.

5. In a stethoscope as claimed in claim 1, 2 or 3 having means for checking that the determined time elapsed is related to the time between similar moments on two adjacent cyclic complexes wherein said means for checking that the determined time elapsed between adjacent crossings is related to the time of a heart cycle includes means for measuring the time tat the complex is above the threshold over a time period sufficiently long for the complex to approach the minimum noise level and checking that the time elapsed is above a minimum associated with a cyclic complex.

6. In a stethoscope as claimed in claim 1, 2 or 3 having means for checking that the determined time elapsed is related to the time between similar moments on two adjacent cyclic complexes wherein said means for checking that the determined time elapsed between adjacent crossings is related to the time of a heart cycle includes means for measuring the time that the complex is above the threshold over a time period sufficiently long for the complex to approach the minimum noise level and checking that the time elapsed is above a minimum associated with a cyclic complex; and

said means for checking that the determined time elapsed is related to the time between two adjacent cyclic complexes includes means for checking that the time is less than a value that is less than 1.2 seconds.

7. In a stethoscope as claimed in claim 1 wherein the base of said wave form is close to the minimum noise level of the sound wave of the heart and said wave form is full wave rectified.

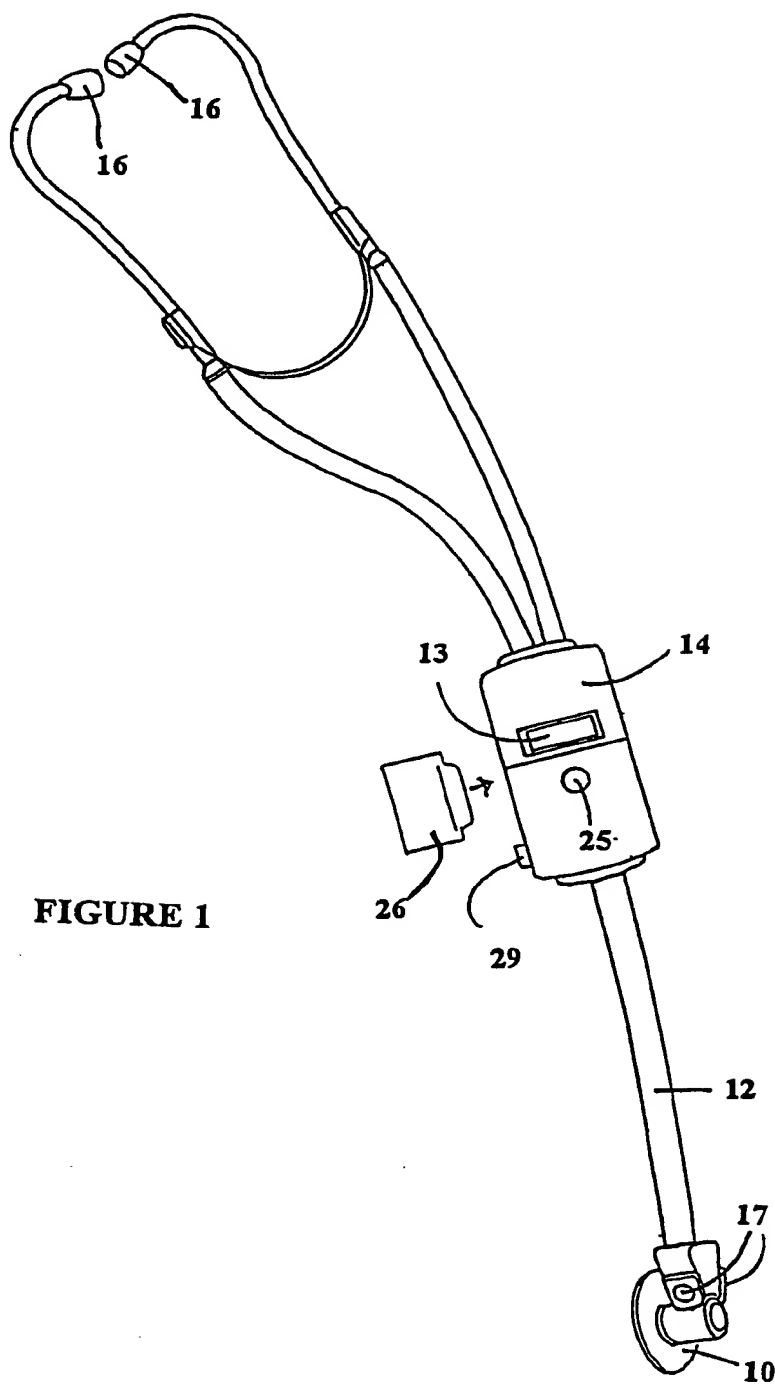


FIGURE 1

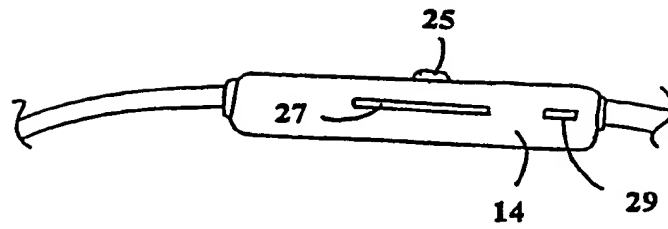


FIGURE 2

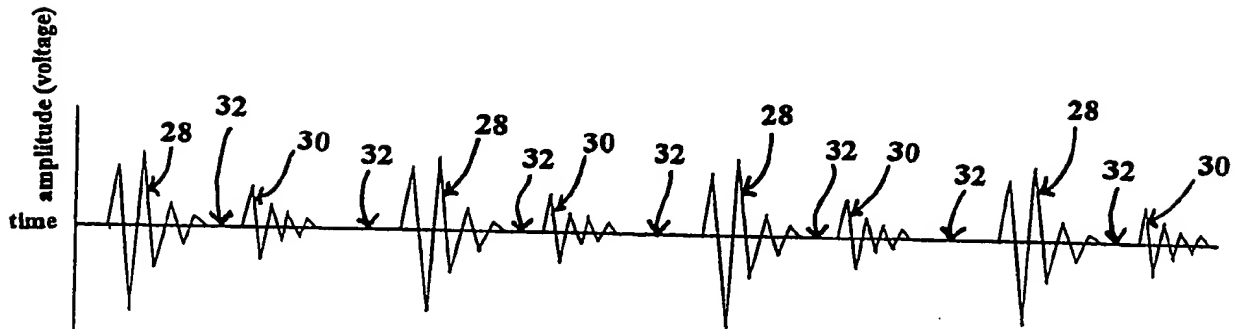


FIGURE 3

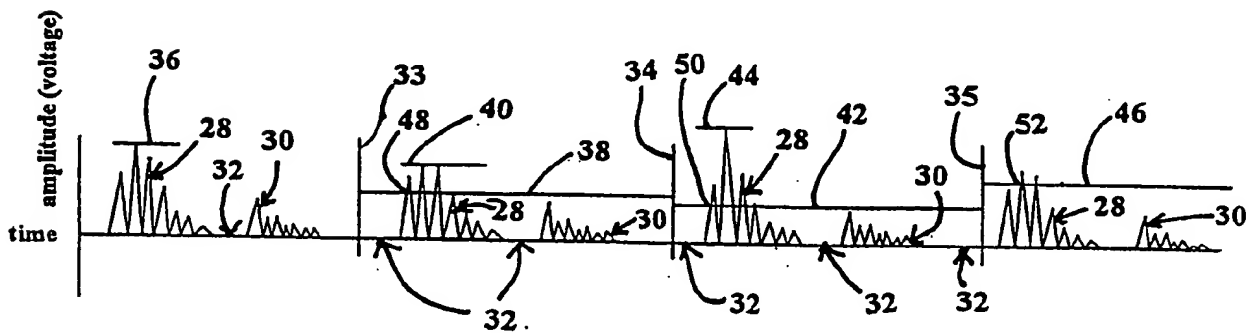


FIGURE 4

INTERNATIONAL SEARCH REPORT

International Application No
PCT/CA 96/00408

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B7/04 A61B5/024

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US,A,4 549 551 (DYCK ET AL.) 29 October 1985 see column 2, line 54 - column 5, line 64 see figure 1	1
A		3,4,7
A	CA,A,1 143 014 (DYCK ET AL.) 15 March 1983 see page 4, line 8 - page 7, line 3 see page 8, line 23 - page 9, line 11	1

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *&* document member of the same patent family

Date of the actual completion of the international search

21 November 1996

Date of mailing of the international search report

- 6. 12. 96

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl,
Fax (+ 31-70) 340-3016

Authorized officer

Chen, A

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/CA 96/00408

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A-4549551	29-10-85	CA-A- 1198806	31-12-85
CA-A-1143014	15-03-83	US-A- 4436096	13-03-84

This Page Blank (uspto)